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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,607	10/11/2001	Kathryn S.E. Cheah	0467/57114-B/RDK/NML	9933

7590

02/06/2004

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EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/975,607	Applicant(s) CHEAH ET AL.	
	Examiner Peter Paras, Jr.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-20 are pending.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-5, in the response received on 11/17/03, is acknowledged. The traversal is on the ground(s) that searching and examining all of the claims of Groups I and II would not present an undue burden for the Examiner. This is not found persuasive because it is maintained the claims of Groups I and II embrace materially different products and different methods of using the products. For example, the claims of Group I are directed to a nucleic acid molecule encoding a mutated collagen X protein and methods of using the same nucleic acid molecule to produce a protein, while the claims of Group II are directed to a mutated collagen X protein and methods of using the same to treat bone disorders. Clearly, the structures of nucleic acid molecules and proteins are different. Moreover, nucleic acid molecules and proteins have separate uses as evidenced by the materially different methods embraced by each of Groups I and II. It is maintained nucleic acid molecules and proteins and their respective methods of use are divergent each from the other as well as separately classified and searched.

Therefore it is maintained that all the inventions are distinct each from the other for the reasons given above. The requirement is still deemed proper and is therefore made FINAL.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the

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Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Claims 6-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response received on 11/17/03.

Drawings

New corrected drawings are required in this application because the figures appear to be photocopies that are illegible due to high background levels. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Priority

The priority statement beginning on line 1 of the specification should be updated to include all priority applications and their respective statuses.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to an isolated DNA comprising the sequence, which codes for a mutated collagen X or portion thereof. The claims are further directed to a vector comprising the same DNA, and a method of producing a polypeptide comprising the same vector and a host.

The specification has described a nucleotide sequence, encoding a mutated collagen X, as set forth in SEQ ID NO: 2. However, the other nucleotide sequences that encode mutated collagen X proteins or portions thereof encompassed within the genus have not been disclosed. Based upon the prior art there is expected to be variation among the species of cDNA, which encode mutated collagen X proteins, because the sequence of collagen X cDNAs would be expected to vary among individuals. The specification discloses a nucleotide sequence, having a 13bp deletion (Col10-13del as set forth in SEQ ID NO: 2) that encodes a mouse mutated collagen X but does not disclose other nucleotide sequences encoding mutated collagen X proteins. There is no

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evidence on the record of a relationship between the structure of any mutated collagen X nucleotide sequence and the claimed mutated collagen X nucleotide sequences that would provide any reliable information about the structure of other mutated collagen X nucleotide sequences within the genus. There is no evidence on the record the nucleotide sequence set forth in SEQ ID NO: 2 had a known structural relationship to any other mutated collagen X nucleotide sequences; the specification discloses only a single mouse mutant collagen X nucleotide sequence; the art indicated that there is variation between collagen X nucleotide sequences. There is no evidence of record that would indicate that any of the claimed mutant collagen X nucleotide sequences, other than SEQ ID NO: 2, or portions thereof, even have the biological activity of regulating bone growth. In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus, because a mouse mutant collagen X nucleotide sequence is not representative of the claimed genus. Consequently, since Applicant was in possession of only the mutant mouse collagen X nucleotide sequence set forth in SEQ ID NO: 2 and since the art recognized variation among the species of the genus of nucleotide sequences that encode collagen X proteins, the mutant mouse collagen X nucleotide sequence was not representative of the claimed genus. Therefore, Applicant was not in possession of the genus of nucleotide sequences encoding mutant collagen X proteins as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in

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sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Note: Limiting the claims to the sequence set forth in SEQ ID NO: 2 may be sufficient to overcome the instant written description rejection.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. This claim is an omnibus type claim. Claims must, under modern claim practice, stand alone to define invention, and incorporation into claims by express reference to specification and/or drawings is not permitted except in very limited circumstances; thus, claims in utility applications that define invention entirely by reference to specification and/or drawings, known as "omnibus" or "formal" claims, are properly rejected under 35 USC 112, paragraph 2, as failing to particularly point out and distinctly claim invention. It is suggested to amend claim 2 such that it is directed to the nucleotide sequence set forth in SEQ ID NO: 2 rather than figure 2.

Claim 4 is incomplete as written. The claim is directed to a method of producing a polypeptide. The claim however is incomplete because no method steps for producing the polypeptide have been provided. Method steps should relate back to the goal of the preamble of the claim in a positive process. Appropriate correction is required. Claim 5 depends from claim 4.

The following proposed claim language may be sufficient to overcome the instant rejection: A method for production of a mutated collagen X polypeptide comprising introducing the vector of claim 3 into an isolated host cell, culturing said host cell whereby said mutated collagen X polypeptide is expressed, and isolating said mutated collagen X polypeptide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Warman et al (Nature Genetics, 1993, 5: 79-82).

The claims are directed to an isolated DNA encoding for a mutated collagen X or a portion thereof and a vector comprising the same DNA.

Warman et al teach an isolated nucleic acid molecule encoding a mutated collagen X protein, wherein the nucleic acid molecule has been inserted into a vector. See page 79 as well as the Methodology section on page 81.

Thus, the teachings of Warman anticipate all of the instant claim limitations.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacenko et al (Nature, 1993, 365: 56-61).

The claims are directed to an isolated DNA encoding for a mutated collagen X or a portion thereof and a vector comprising the same DNA as well as a method of producing a polypeptide.

Jacenko et al teach an isolated nucleic acid sequence encoding a mutated collagen X, wherein the nucleic acid sequence has been inserted into a vector. See pages 56-57 and also figure 1 on page 57. Jacenko further teach production of mutated collagen X polypeptides in vitro. See page 57 and the figure 1 legend.

Thus, the teachings of Jacenko et al anticipate all of the instant claim limitations.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-7 of U.S. Patent No. 6,369,295. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims embrace nucleotide sequences encoding mutated collagen X proteins. The claims of the instant application are directed to a genus of nucleotide sequences encoding mutated collagen X proteins, while the claims of US 6,369,295 are directed to the nucleotide sequence set forth in SEQ ID NO: 2, a species of nucleotide sequence encoding a mutated collagen X protein, which would anticipate the instant claims.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 2 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 6 of prior U.S. Patent No. 6,369,295. This is a double patenting rejection.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

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**PETER PARAS
PATENT EXAMINER**

A handwritten signature in cursive script that reads "Pete Paras".